Introduced by Assembly Member Jones

February 26, 2009

An act to amend Sections 1200, 1204, 1206, and 1248.1 of, and to add Sections 1204.6, 1212.5, 1212.6, and 1212.7 to, the Health and Safety Code, relating to public health.

LEGISLATIVE COUNSEL'S DIGEST

AB 832, as introduced, Jones. Clinic licensing.

(1) Existing law establishes various programs for the prevention of disease and the promotion of the public health under the jurisdiction of the State Department of Public Health, including, but not limited to, provisions for the licensing, with certain exceptions, of clinics, as defined. A violation of these provisions is a crime.

This bill would exclude a place, establishment, or institution that solely provides immunizations, or screenings for blood pressure, cholesterol, or bone density, or a combination of those services, from the definition of "clinic" for these purposes.

(2) Existing law defines "surgical clinic" as a clinic that provides ambulatory surgical care and is not part of a hospital or is a place that is owned, leased, or operated as a clinic or office by one or more physicians or dentists.

This bill would recast that definition, would define "ambulatory surgical care" for this purpose, and would delete the exemption for a place that is owned, leased, or operated by one or more physicians or dentists. The bill would require surgical clinics to be licensed regardless of physician ownership, but would exclude a doctor's office or other

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place that provides only prescribed services, and would make conforming changes.

This bill would require any person seeking licensure as a surgical clinic to provide documentation of satisfactory completion of prescribed structural building requirements.

By changing the definition of an existing crime, this bill would impose a state-mandated local program.

This bill would declare the intent of the Legislature to subsequently appropriate funds to the department as a loan to support the licensing and certification program relating to surgical clinics.

(3) The California Constitution requires the state to reimburse local agencies and school districts for certain costs mandated by the state. Statutory provisions establish procedures for making that reimbursement.

This bill would provide that no reimbursement is required by this act for a specified reason.

Vote: majority. Appropriation: no. Fiscal committee: yes. State-mandated local program: ves.

The people of the State of California do enact as follows:

- 1 SECTION 1. This act shall be known, and may be cited, as the California Outpatient Surgery Patient Safety and Improvement
- 3 Act.
- 4 SEC. 2. Section 1200 of the Health and Safety Code is amended 5 to read:
- 6 1200. As used in this chapter, "clinic" means an organized 7 outpatient health facility-which that provides direct medical,
- surgical, dental, optometric, or podiatric advice, services, or
- treatment to patients who remain less than 24 hours, and which
- 10 may also provide diagnostic or therapeutic services to patients in
- 11 the home as an incident to care provided at the clinic facility.
- 12 Nothing in this section shall be construed to prohibit the provision
- of nursing services in a clinic licensed pursuant to this chapter. In 13
- 14 no case shall a clinic be deemed to be a health facility subject to
- the provisions of Chapter 2 (commencing with Section 1250) of 15 16 this division. A place, establishment, or institution—which that
- 17
- solely provides advice, counseling, information, or referrals on 18
- the maintenance of health or on the means and measures to prevent
- 19 or avoid sickness, disease, or injury, where such advice, counseling,
- 20 information, or referrals does not constitute the practice of

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medicine, surgery, dentistry, optometry, or podiatry, shall not be deemed a clinic for purposes of this chapter. A place, establishment, or institution that solely provides immunizations, or screenings for blood pressure, cholesterol, or bone density, or any combination of these services, shall not be deemed a clinic for purposes of this chapter.

References in this chapter to "primary care clinics" shall mean and designate all the types of clinics specified in subdivision (a) of Section 1204, including community clinics and free clinics. References in this chapter to specialty clinics shall mean and designate all the types of clinics specified in subdivision (b) of Section 1204, including surgical clinics, chronic dialysis clinics, and rehabilitation clinics.

- SEC. 3. Section 1204 of the Health and Safety Code is amended to read:
- 1204. Clinics eligible for licensure pursuant to this chapter are primary care clinics and specialty clinics.
- (a) (1) Only the following defined classes of primary care clinics shall be eligible for licensure:
- (A) A "community clinic" means a clinic operated by a tax-exempt nonprofit corporation that is supported and maintained in whole or in part by donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. In a community clinic, any charges to the patient shall be based on the patient's ability to pay, utilizing a sliding fee scale. No corporation other than a nonprofit corporation, exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954 as amended, or a statutory successor thereof, shall operate a community clinic; provided, that the licensee of any community clinic so licensed on the effective date of this section shall not be required to obtain tax-exempt status under either federal or state law in order to be eligible for, or as a condition of, renewal of its license. No natural person or persons shall operate a community clinic.
- (B) A "free clinic" means a clinic operated by a tax-exempt, nonprofit corporation supported in whole or in part by voluntary donations, bequests, gifts, grants, government funds or contributions, that may be in the form of money, goods, or services. In a free clinic there shall be no charges directly to the patient for services rendered or for drugs, medicines, appliances, or

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apparatuses furnished. No corporation other than a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954 as amended, or a statutory successor thereof, shall operate a free clinic; provided, that the licensee of any free clinic so licensed on the effective date of this section shall not be required to obtain tax-exempt status under either federal or state law in order to be eligible for, or as a condition of, renewal of its license. No natural person or persons shall operate a free clinic.

- (2) Nothing in this subdivision shall prohibit a community clinic or a free clinic from providing services to patients whose services are reimbursed by third-party payers, or from entering into managed care contracts for services provided to private or public health plan subscribers, as long as the clinic meets the requirements identified in subparagraphs (A) and (B). For purposes of this subdivision, any payments made to a community clinic by a third-party payer, including, but not limited to, a health care service plan, shall not constitute a charge to the patient. This paragraph is a clarification of existing law.
- (b) The following types of specialty clinics shall be eligible for licensure as specialty clinics pursuant to this chapter:
- (1) A "surgical clinic" means a clinic that is not part of a hospital or a primary care clinic that is either licensed pursuant to this section, or exempt pursuant to subdivision (b) of Section 1206, and that provides ambulatory surgical care as defined in Section 1204.6 for patients who remain less than 24 hours. A surgical clinic does not include any place or establishment owned or leased and operated as a clinic or office by one or more physicians or dentists in individual or group practice, regardless of the name used publicly to identify the place or establishment, provided, however, that physicians or dentists may, at their option, apply for licensure. Surgical clinics shall be subject to licensure by the department regardless of physician ownership.
- (2) A "chronic dialysis clinic" means a clinic that provides less than 24-hour care for the treatment of patients with end-stage renal disease, including renal dialysis services.
- (3) A "rehabilitation clinic" means a clinic that, in addition to providing medical services directly, also provides physical rehabilitation services for patients who remain less than 24 hours. Rehabilitation clinics shall provide at least two of the following

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rehabilitation services: physical therapy, occupational therapy, social, speech pathology, and audiology services. A rehabilitation clinic does not include the offices of a private physician in individual or group practice.

- (4) An "alternative birth center" means a clinic that is not part of a hospital and that provides comprehensive perinatal services and delivery care to pregnant women who remain less than 24 hours at the facility.
- (c) In accordance with subdivision (d) of Section 1248.1, licensure as a surgical clinic shall satisfy the requirements of Chapter 1.3 (commencing with Section 1248).
- SEC. 4. Section 1204.6 is added to the Health and Safety Code, to read:
 - 1204.6. (a) "Ambulatory surgical care" for purposes of licensure as a surgical clinic, means the incision, partial or complete excision, destruction, resection, or other structural alteration of human tissue by any means except any of the following:
 - (1) Minor skin repair procedures, including, but not limited to, any of the following:
 - (A) Repair of minor lacerations.

- (B) Excision of moles, warts, or other minor skin lesions.
- (C) Incision and drainage of superficial abscesses.
- (2) Procedures using only local anesthesia, topical anesthesia, or no anesthesia.
- (3) Procedures not using general anesthesia or conscious sedation.
- (b) "General anesthesia" for purposes of licensure as a surgical clinic, means a controlled state of depressed consciousness or unconsciousness, accompanied by partial or complete loss of protective reflexes, produced by a pharmacologic or nonpharmacologic method, or a combination thereof.
- (c) "Conscious sedation" for purposes of licensure as a surgical clinic, means a minimally depressed level of consciousness produced by a pharmacologic or nonpharmacologic method, or a combination thereof, that retains the patient's ability to maintain independently and continuously an airway, and respond appropriately to physical stimulation or verbal command. Conscious sedation does not include the administration of oral medications or the administration of a mixture of nitrous oxide

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1 and oxygen, whether administered alone or in combination with 2 each other.

- (d) A doctor's office or other place, establishment, or institution that provides no surgical services other than those described in paragraphs (1), (2), and (3) of subdivision (a) shall not be required to obtain licensure as a surgical clinic.
- 7 SEC. 5. Section 1206 of the Health and Safety Code is amended 8 to read:
 - 1206. This The licensure and other requirements of this chapter does do not apply to any of the following:
 - (a) Except with respect to the option provided with regard to surgical clinics in paragraph (1) of subdivision (b) of Section 1204 and, further, with respect to specialty clinics specified in paragraph (2) of subdivision (b) of Section 1204, any Any place or establishment owned or leased and operated as a clinic or office by one or more licensed health care practitioners and used by the practitioner as an office for the practice of their his or her profession, within the scope of their his or her license in any lawful form of organization, so long as each licensed health care practitioner who practices at the clinic has some ownership or leasehold interest in, and some degree of control over and responsibility for, the operation of the clinic, regardless of the name used publicly to identify the place or establishment. The exemption pursuant to this subdivision shall not apply to either of the following:
 - (1) Any surgical clinic as described in paragraph (1) of subdivision (b) of Section 1204, regardless of any health care practitioner ownership interest in the clinic.
 - (2) Any chronic dialysis clinic as described in paragraph (2) of subdivision (b) of Section 1204.
 - (b) Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies, and any primary care clinic specified in subdivision (a) of Section 1204 that is directly conducted, maintained, or operated by this state or by any of its political subdivisions or districts, or by any city. Nothing in this subdivision precludes the state department from adopting regulations that utilize clinic licensing standards as eligibility criteria for participation in programs funded wholly or partially under Title XVIII or XIX of the federal Social Security Act.

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(c) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1601 of Title 25 of the United States Code, that is located on land recognized as tribal land by the federal government.

- (d) Clinics conducted, operated, or maintained as outpatient departments of hospitals.
- (e) Any facility licensed as a health facility under Chapter 2 (commencing with Section 1250).
- (f) Any freestanding clinical or pathological laboratory licensed under Chapter 3 (commencing with Section 1200) of Division 2 of the Business and Professions Code.
- (g) A clinic operated by, or affiliated with, any institution of learning that teaches a recognized healing art and is approved by the state board or commission vested with responsibility for regulation of the practice of that healing art. The exemption pursuant to this subdivision shall not apply to any surgical clinic as described in paragraph (1) of subdivision (b) of Section 1204.
- (h) A clinic that is operated by a primary care community or free clinic and that is operated on separate premises from the licensed clinic and is only open for limited services of no more than 20 hours a week. An intermittent clinic as described in this subdivision shall, however, meet all other requirements of law, including administrative regulations and requirements, pertaining to fire and life safety.
- (i) The offices of physicians in group practice who provide a preponderance of their services to members of a comprehensive group practice prepayment health care service plan subject to Chapter 2.2 (commencing with Section 1340).
- (j) Student health centers operated by public institutions of higher education.
- (k) Nonprofit speech and hearing centers, as defined in Section 1201.5. Any nonprofit speech and hearing clinic desiring an exemption under this subdivision shall make application therefor to the director, who shall grant the exemption to any facility meeting the criteria of Section 1201.5. Notwithstanding the licensure exemption contained in this subdivision, a nonprofit speech and hearing center shall be deemed to be an organized outpatient clinic for purposes of qualifying for reimbursement as a rehabilitation center under the Medi-Cal Act (Chapter 7

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(commencing with Section 14000) of Part 3 of Division 9 of the 2 Welfare and Institutions Code).

- (l) A clinic operated by a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, that conducts medical research and health education and provides health care to its patients through a group of 40 or more physicians and surgeons, who are independent contractors representing not less than board-certified specialties, and not less than two-thirds of whom practice on a full-time basis at the clinic.
- (m) Any clinic, limited to in vivo diagnostic services by magnetic resonance imaging functions or radiological services under the direct and immediate supervision of a physician and surgeon who is licensed to practice in California. This shall not be construed to permit cardiac catheterization or any treatment modality in these clinics.
- (n) A clinic operated by an employer or jointly by two or more employers for their employees only, or by a group of employees, or jointly by employees and employers, without profit to the operators thereof or to any other person, for the prevention and treatment of accidental injuries to, and the care of the health of, the employees comprising the group.
- (o) A community mental health center, as defined in Section 5601.5 of the Welfare and Institutions Code.
- (p) (1) A clinic operated by a nonprofit corporation exempt from federal income taxation under paragraph (3) of subsection (c) of Section 501 of the Internal Revenue Code of 1954, as amended, or a statutory successor thereof, as an entity organized and operated exclusively for scientific and charitable purposes and that satisfied all of the following requirements on or before January 1, 2005:
- (A) Commenced conducting medical research on or before January 1, 1982, and continues to conduct medical research.
- (B) Conducted research in, among other areas, prostatic cancer, cardiovascular disease, electronic neural prosthetic devices, biological effects and medical uses of lasers, and human magnetic resonance imaging and spectroscopy.
- (C) Sponsored publication of at least 200 medical research 40 articles in peer-reviewed publications.

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- 1 (D) Received grants and contracts from the National Institutes 2 of Health.
 - (E) Held and licensed patents on medical technology.
 - (F) Received charitable contributions and bequests totaling at least five million dollars (\$5,000,000).
 - (G) Provides health care services to patients only:

- (i) In conjunction with research being conducted on procedures or applications not approved or only partially approved for payment (I) under the Medicare program pursuant to Section 1359y(a)(1)(A) of Title 42 of the United States Code, or (II) by a health care service plan registered under Chapter 2.2 (commencing with Section 1340), or a disability insurer regulated under Chapter 1 (commencing with Section 10110) of Part 2 of Division 2 of the Insurance Code; provided that services may be provided by the clinic for an additional period of up to three years following the approvals, but only to the extent necessary to maintain clinical expertise in the procedure or application for purposes of actively providing training in the procedure or application for physicians and surgeons unrelated to the clinic.
- (ii) Through physicians and surgeons who, in the aggregate, devote no more than 30 percent of their professional time for the entity operating the clinic, on an annual basis, to direct patient care activities for which charges for professional services are paid.
- (H) Makes available to the public the general results of its research activities on at least an annual basis, subject to good faith protection of proprietary rights in its intellectual property.
- (I) Is a freestanding clinic, whose operations under this subdivision are not conducted in conjunction with any affiliated or associated health clinic or facility defined under this division, except a clinic exempt from licensure under subdivision (m). For purposes of this subparagraph, a freestanding clinic is defined as "affiliated" only if it directly, or indirectly through one or more intermediaries, controls, or is controlled by, or is under common control with, a clinic or health facility defined under this division, except a clinic exempt from licensure under subdivision (m). For purposes of this subparagraph, a freestanding clinic is defined as "associated" only if more than 20 percent of the directors or trustees of the clinic are also the directors or trustees of any individual clinic or health facility defined under this division, except a clinic exempt from licensure under subdivision (m). Any activity by a

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clinic under this subdivision in connection with an affiliated or associated entity shall fully comply with the requirements of this subdivision. This subparagraph shall not apply to agreements between a clinic and any entity for purposes of coordinating medical research.

- (2) By January 1, 2007, and every five years thereafter, the Legislature shall receive a report from each clinic meeting the criteria of this subdivision and any other interested party concerning the operation of the clinic's activities. The report shall include, but not be limited to, an evaluation of how the clinic impacted competition in the relevant health care market, and a detailed description of the clinic's research results and the level of acceptance by the payer community of the procedures performed at the clinic. The report shall also include a description of procedures performed both in clinics governed by this subdivision and those performed in other settings. The cost of preparing the reports shall be borne by the clinics that are required to submit them to the Legislature pursuant to this paragraph.
- SEC. 6. Section 1212.5 is added to the Health and Safety Code, to read:
- 1212.5. (a) Commencing January 1, 2010, in addition to other licensing requirements of this chapter, any person, firm, association, partnership, or corporation seeking a license for a surgical clinic shall provide the department with documentation of satisfactory completion of the structural and building requirements set forth in Section 1226 of Title 24 of the California Code of Regulations, or compliance with the 2000 Medicare Life and Safety Code requirements.
- (b) Commencing January 1, 2010, a surgical clinic shall also meet all of the following standards:
- (1) Only those patients who have given full informed consent about the inherent risks of receiving surgery in facilities with limited post surgical rescue potential that would be available in a general acute care hospital shall receive services in the surgical clinic.
- (2) Comply with the conditions of coverage as set forth in Subpart C of Part 416 of Title 42 of the Code of Federal Regulations, as those conditions exist on January 1, 2008. The conditions of coverage shall be conditions of providing services regardless of the source of payment for those services.

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1 (3) Limit surgical procedures to those that comply with all of the following:

- (A) Do not require the presence of more than one surgeon during the procedure.
 - (B) Are not expected to require a blood transfusion.
- (C) Are not expected to require major or prolonged invasion of body cavities.
 - (D) Are not expected to involve major blood vessels.
 - (E) Are not inherently life threatening.
- (F) Are not emergency surgeries.

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- (G) Are not experimental surgeries.
- (4) A preanesthesia evaluation, including an ASA Physical Status Classification, shall be completed on all surgical anesthesia patients. Surgical procedures shall not be performed on a patient with severe systemic disease that is a constant threat to life (ASA Classification 4) or on a moribund patient who is not expected to survive for 24 hours without the operation (ASA Classification 5). A patient with severe systemic disease (ASA Classification 3) shall have a presurgical consultation with a physician specialist appropriate for the patient's severe systemic disease in order to obtain medical clearance for surgery.
 - (5) Establish and implement policies and procedures compliant with the conditions of coverage. The policies and procedures shall comply with both of the following:
- (A) The policies and procedures shall include, but need not be limited to, all of the following:
- (i) Surgical services, as provided by physicians, dentists, or podiatrists.
- 29 (ii) Anesthesia services.
- 30 (iii) Nursing services.
- 31 (iv) Evaluation of quality assessment and performance improvement.
- 33 (v) Infection control.
- 34 (vi) Pharmaceutical services.
- 35 (vii) Laboratory and radiology services.
- 36 (viii) Housekeeping services, including provisions for maintenance of a safe, clean environment.
- 38 (ix) Patient health records, including provisions that shall be 39 developed with the assistance of a person skilled in record 40 maintenance and preservation.

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 (x) Personnel policies and procedures.

- (B) The policies and procedures shall provide for appropriate staffing ratios for all care provided to patients receiving general anesthesia in compliance with both of the following:
- (i) In each surgical room there shall be at least one registered nurse assigned to the duties of the circulating nurse and a minimum of one additional person serving as scrub assistant for each patient-occupied operating room. The scrub assistant may be a licensed nurse, an operating room technician, or other person who has demonstrated current competence to the clinic as a scrub assistant, but shall not be a physician or other licensed health professional who is assisting in the performance of surgery.
- (ii) The licensed nurse-to-patient ratio in a postanesthesia recovery unit of the anesthesia service shall be one-to-two or fewer at all times, regardless of the type of general anesthesia the patient receives.
- 17 SEC. 7. Section 1212.6 is added to the Health and Safety Code, to read:
 - 1212.6. Every clinic for which a license has been issued under Section 1212.5 shall be subject to the reporting requirements contained in Section 1279.1 and the penalties imposed under Sections 1280.1, 1280.3, and 1280.4.
 - SEC. 8. Section 1212.7 is added to the Health and Safety Code, to read:
 - 1212.7. It is the intent of the Legislature to provide funding through an appropriation in the Budget Act or other measure to the State Department of Public Health, for a loan for the support the operations of the Licensing and Certification Program for activities authorized by this chapter relating to the licensure of surgical clinics. The loan shall be repaid with proceeds from fees collected pursuant to Section 1266.
 - SEC. 9. Section 1248.1 of the Health and Safety Code is amended to read:
 - 1248.1. No association, corporation, firm, partnership, or person shall operate, manage, conduct, or maintain an outpatient setting in this state, unless the setting is one of the following:
- 37 (a) An ambulatory surgical center that is certified to participate 38 in the Medicare program under Title XVIII (42 U.S.C. Sec. 1395 39 et seq.) of the federal Social Security Act.

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(b) Any clinic conducted, maintained, or operated by a federally recognized Indian tribe or tribal organization, as defined in Section 450 or 1601 of Title 25 of the United States Code, and located on land recognized as tribal land by the federal government.

- (c) Any clinic directly conducted, maintained, or operated by the United States or by any of its departments, officers, or agencies.
- (d) Any primary care clinic licensed under subdivision (a) and any surgical clinic licensed under subdivision (b) of Section 1204.
- (e) Any health facility licensed as a general acute care hospital under Chapter 2 (commencing with Section 1250).
- (f) Any outpatient setting to the extent that it is used by a dentist or physician and surgeon in compliance with Article 2.7 (commencing with Section 1646) or Article 2.8 (commencing with Section 1647) of Chapter 4 of Division 2 of the Business and Professions Code.
- (g) An outpatient setting accredited by an accreditation agency approved by the division pursuant to this chapter.
- (h) A setting, including, but not limited to, a mobile van, in which equipment is used to treat patients admitted to a facility described in subdivision (a), (d), or (e), and in which the procedures performed are staffed by the medical staff of, or other healthcare practitioners with clinical privileges at, the facility and are subject to the peer review process of the facility but which setting is not a part of a facility described in subdivision (a), (d), or (e).

Nothing in this section shall relieve an association, corporation, firm, partnership, or person from complying with all other provisions of law that are otherwise applicable, *including, but not limited to, licensure as a primary care or specialty clinic as set forth in Chapter 1 (commencing with Section 1200) of Division 2 of the Health and Safety Code. Surgical clinics shall be subject to licensure regardless of any physician ownership interest.*

SEC. 10. No reimbursement is required by this act pursuant to Section 6 of Article XIIIB of the California Constitution because the only costs that may be incurred by a local agency or school district will be incurred because this act creates a new crime or infraction, eliminates a crime or infraction, or changes the penalty for a crime or infraction, within the meaning of Section 17556 of the Government Code, or changes the definition of a crime within

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- 1 the meaning of Section 6 of Article XIIIB of the California
- 2 Constitution.